K050898

MAY 25 2005

Endoscopy
Smith & Nephew, Inc
150 Minuteman Road
Andover, MA 01810

978 749 1000
978 749 1599 Fax
www.smith-nephew.com

We are **smith&nephew**

SECTION IV

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew Vulcan Articular Cartilage Probe

Date Prepared: December 13, 2004

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division

150 Minuteman Road

Andover, MA 01810

B. Company Contact

Karen Provencher

Regulatory Affairs Specialist

P: 978-749-1365; F: 978-749-1443

C. Device Name

Trade Name:	Smith & Nephew Vulcan Articular Cartilage Probe
Common Name:	Monopolar Electrosurgical Probe
Classification Name:	Device, Electrosurgical Cutting and Coagulation and accessories (per 21 CFR § 878.4400)

D. Predicate Devices

The Smith & Nephew Smith & Nephew Vulcan Articular Cartilage Probe is substantially equivalent in intended use and fundamental scientific technology to the following legally marketed device in commercial distribution: Smith & Nephew Vulcan TAC C II Probe (K003198 formerly owned by Oratec Interventions, Inc.).

E. Description of Device

The Smith & Nephew Vulcan Articular Cartilage Probe is a single-use, monopolar radiofrequency probe which incorporates a pivoting ceramic head with an embedded RF electrode; protective sheath; and integrated cable. It requires a split ground pad and it is designed for use only with the Smith & Nephew Vulcan Generator.

F. Intended Use

The Smith & Nephew Vulcan Articular Cartilage Probe is indicated for arthroscopic chondroplasty procedures in the knee, shoulder, wrist, hip, etc.

G. Comparison of Technological Characteristics

The Smith & Nephew Vulcan Articular Cartilage Probe is similar to the Smith & Nephew Vulcan TAC C II Probe in that both devices are monopolar, single use devices. Both probes require a split grounding pad and are designed for use only with the Smith & Nephew Vulcan Generator. The Smith & Nephew Vulcan Articular Cartilage Probe represents a specific indication for use within the scope of the cleared indications for the Smith & Nephew TAC C II Probe. A major technological difference between the two probes is that the Smith & Nephew Vulcan TAC C II Probe is temperature controlled and the Smith & Nephew Vulcan Articular Cartilage Probe is power controlled. Bench testing confirms substantial equivalence in performance characteristics.

H. Summary Performance Data

There are no known performance standards or special controls promulgated under section 415 of the Act for this device. The device was tested and found to be in compliance with ISO 10993-1, ANSI/AAMI HF-18 and IEC 60601-2-2. At the time of commercialization, the device will be incompliance with applicable sterilization standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2005

Smith and Nephew Incorporated
C/o Mr. J.A. Van Vugt
Kema Quality B.V.
4377 County Line Road
Chalfont, Pennsylvania 18914

Re: K050898
Trade/Device Name: Smith and Nephew Vulcan Articular Cartilage Probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, HRX
Dated: May 13, 2005
Received: May 16, 2005

Dear Mr. Vugt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Smith & Nephew Vulcan Articular Cartilage Probe

Indications For Use:

The Smith & Nephew Vulcan Articular Cartilage Probe is indicated for use in arthroscopic chondroplasty procedures in the knee, shoulder, wrist, hip, etc.

Prescription Use ___x_____ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K050898